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*Attorneys for Plaintiffs
Teva Branded Pharmaceutical Products
R&D Inc. and Norton (Waterford) Ltd.*

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

TEVA BRANDED PHARMACEUTICAL
PRODUCTS R&D, INC., and
NORTON (WATERFORD) LTD.,

Plaintiffs,

v.

CIPLA USA, INC. and CIPLA LTD.,

Defendants.

Civil Action No. 24-909 (SRC)(MAH)
(consolidated)

Civil Action No. 24-5856 (SRC)(MAH)

Civil Action No. 24-7162 (SRC)(MAH)

~~SEPI-RELATED~~ DISCOVERY CONFIDENTIALITY ORDER

WHEREAS, plaintiffs Teva Branded Pharmaceutical Products R&D, Inc. (“Teva”), and Norton (Waterford) Ltd. (“Norton”) (collectively, “Plaintiffs”) and defendants Cipla USA, Inc. and Cipla Ltd. (collectively, “Cipla”) recognize the discovery in the above-entitled litigation (the “Action”) may involve the disclosure of certain documents, things, and information in the possession, custody, or control of a party or non-party that constitute trade secrets or other

confidential information within the meaning of Rule 26(c) of the Federal Rules of Civil Procedure;

WHEREAS, the parties, through counsel, stipulate to the entry of this Protective Order to prevent unnecessary dissemination or disclosure of such confidential information; and

WHEREAS, the parties, through counsel, stipulate that good cause as set forth in *Pansy v. Borough of Stroudsburg*, 23 F.3d 772 (3d Cir. 1994) and *Glenmede Trust Co. v. Thompson*, 56 F.3d 476 (3d Cir. 1995) exists for the entry of this Protective Order pursuant to Fed. R. Civ. P. 26(c) to protect against improper disclosure or use of confidential information produced in this case.

IT IS HEREBY ORDERED AS FOLLOWS:

1. This Order shall be applicable to and govern all deposition, documents and things produced in response to requests for production, answers to interrogatories, responses to requests for admission, documents produced in response to subpoenas, and all other discovery taken pursuant to the Federal Rules of Civil Procedure and other information which the party designates pursuant to this Order furnished, directly or indirectly, in this Action.

2. Any party to this litigation and any third-party shall have the right to designate as “Confidential” and subject to this Order any information, document, or thing, or portion of any document or thing: (a) that contains trade secrets, competitively sensitive technical, marketing, financial, sales or other confidential business information, or (b) that contains private or confidential personal information, or (c) that contains information received in confidence from third parties, or (d) which the producing party otherwise believes in good faith to be entitled to protection under Federal Rule of Civil Procedure Rule 26(c)(1)(G) and Local Civil Rule 5.3. Any party to this litigation or any third party covered by this Order, who produces or discloses

any Confidential material, including without limitation any information, document, thing, interrogatory answer, admission, pleading, or testimony, shall mark the same with the foregoing or similar legend: “CONFIDENTIAL” or “CONFIDENTIAL – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER” (hereinafter “Confidential”). Any information, document, or thing, or portion of any document or thing produced in this matter shall be deemed produced in any case consolidated herewith.

3. All Confidential material shall be used by the receiving party solely for purposes of the prosecution or defense of this Action, and shall not be used by the receiving party for any business, commercial, competitive, personal, or other purpose, and shall not be disclosed by the receiving party to anyone other than those set forth in Paragraph 6, unless and until the restrictions herein are removed either by written agreement of counsel for the parties, or by Order of the Court. It is, however, understood that counsel for a party may give advice and opinions to his or her client solely relating to the above-captioned action based on his or her evaluation of Confidential material, provided that such advice and opinions shall not reveal the content of such Confidential material except by prior written agreement of counsel for the parties, or by Order of the Court.

4. Absent consent of the producing parties and/or further order of this Court, all persons receiving information designated Confidential under this Discovery Confidentiality Order from an opposing party in this action are expressly prohibited from using or disclosing such information in connection with any practice before or communication with the United States Patent and Trademark Office (“PTO”) or the Patent Trial and Appeal Board (“PTAB”), the United States Food and Drug Administration (“FDA”) (including in connection with Citizens Petitions), the United States Pharmacopoeia, or their counterpart organizations in any foreign

jurisdiction, and are expressly prohibited from using or disclosing such information in connection with any other civil action.

5. Absent consent of the producing parties and/or further order of this Court, any person who received information designated Confidential information under this Discovery Confidentiality Order from an opposing party shall not, thereafter during the course of this action and continuing for two year following final termination of this action, work on or participate in, directly or indirectly, (i) the preparation, prosecution, or supervision of, or the substantive assistance with, the drafting, amending, or editing of any patent application or claims (foreign or domestic) directed to any pharmaceutical compounds or compositions, including inhaler products, containing beclomethasone dipropionate, or any inhaler or dose counter of an inhaler used for any active ingredient, and do not, formally or informally, amend, draft, or otherwise substantially assist in the drafting or amending of such patent claims in any post-grant process (e.g., inter partes reviews, post grant reviews or reissue or reexamination proceedings at the U.S. Patent and Trademark Office or the Patent trial and Appeal Board or pre- or post-grant opposition proceedings or invalidation proceedings before a foreign patent office or court) or (ii) engage, formally or informally, in the preparation or supervision of, or the substantive assistance with, any FDA proceedings relating to beclomethasone dipropionate, or any inhaler or dose counter of an inhaler used for any active ingredient, including the drafting or editing of a Citizen Petition (or related submission, including a response to a Citizen Petition) concerning any inhaler product containing beclomethasone dipropionate, or any dose counter of an inhaler used for any active ingredient. For clarity, except for drafting, amending, editing, or crafting claims, nothing in item (i) of this paragraph shall prevent an individual who receives Confidential information from working on or participating in, directly or indirectly, inter partes reviews, post grant

reviews, or re-issue or re-examination proceedings at the PTO or PTAB or pre- or post-grant opposition proceedings or invalidation proceedings before a foreign patent office or court related to any pharmaceutical compounds or compositions, including inhaler products, containing beclomethasone dipropionate, or any inhaler or dose counter of an inhaler used for any active ingredient. For further clarity, nothing in item (ii) of this paragraph shall prevent an individual who receives Confidential information from working on or participating in, directly or indirectly, the drafting or editing of submissions to the FDA that are not Citizen Petitions or related submissions, including but not limited to submissions related to the listing of a patent in the Orange Book.

6. Confidential material and the contents of Confidential material may be disclosed only to the following individuals under the following conditions:

- (a) Outside counsel (herein defined as any attorney at the parties' outside law firms), provided such attorneys do not (i) work on or participate in, directly or indirectly, the preparation, prosecution, or supervision of, or the substantive assistance with, the drafting, amending, or editing of any patent application or claims (foreign or domestic) directed to any pharmaceutical compounds or compositions, including inhaler products, containing beclomethasone dipropionate, or any inhaler or dose counter of an inhaler used for any active ingredient, and do not, formally or informally, amend, draft, or otherwise substantially assist in the drafting or amending of such patent claims in any post-grant processed (e.g., inter partes reviews, post grant reviews or reissue or reexamination proceedings at the U.S. Patent and Trademark Office or the Patent trial and Appeal Board or pre- or post-grant opposition proceedings or invalidation proceedings before a foreign patent

office or court) or (ii) petition or otherwise engage with the FDA to prohibit or otherwise limit sales of an Abbreviated New Drug Application that refers or relates to Qvar® RediHaler, beclomethasone dipropionate, or any inhaler or dose counter of an inhaler used for any active ingredient, including the drafting or editing of a Citizen Petition (or related submission, including a response to a Citizen Petition) concerning any pharmaceutical compounds or compositions, including inhaler products, containing beclomethasone dipropionate, or any inhaler or dose counter of an inhaler used for any active ingredient, subject to the clarifications provided in Paragraph 7. The restrictions of this Order continue to apply to any person who is, or was at any time, designated under this paragraph.

- (b) Up to (4) in-house personnel for the parties, each of whom (i) is an attorney or counsel, or if not an attorney or counsel, is in the intellectual property or legal department/division of said party, (ii) is responsible for overseeing this litigation, (iii) has executed the non-disclosure agreement in the form attached hereto as Exhibit A, and (iv) does not, (1) work on or participate in, directly or indirectly, the preparation, prosecution, or supervision of, or the substantive assistance with, the drafting, amending, or editing of any patent application or claims (foreign or domestic) directed to any pharmaceutical compounds or compositions, including inhaler products, containing beclomethasone dipropionate, or any inhaler or dose counter of an inhaler used for any active ingredient, and do not, formally or informally, amend, draft, or otherwise substantially assist in the drafting or amending of such patent claims in any post-grant processed (e.g., inter partes reviews, post grant reviews or reissue or reexamination proceedings at the U.S.

Patent and Trademark Office or the Patent trial and Appeal Board or pre- or post-grant opposition proceedings or invalidation proceedings before a foreign patent office or court) or (2) petition or otherwise engage with the FDA to prohibit or otherwise limit sales of an Abbreviated New Drug Application that refers or relates to Qvar® RediHaler, beclomethasone dipropionate, or any inhaler or dose counter of an inhaler used for any active ingredient, including the drafting or editing of a Citizen Petition (or related submission, including a response to a Citizen Petition) concerning any inhaler product containing beclomethasone dipropionate, or any inhaler or dose counter of an inhaler used for any active ingredient, subject to the clarifications provided in Paragraph 7, and (3) the executed copy of Exhibit A has been provided to the opposing party. The parties designate the following people pursuant to this paragraph. If a party wishes to substitute another individual in this paragraph, the party must notify all other parties to this Order. The restrictions of this Order continue to apply to any person who is, or was at any time, designated under this paragraph.

For Teva: Colman Ragan, VP & General Counsel North America IP Litigation

Rivka Jungreis, Assoc. General Counsel North America IP
Litigation

Lori Wolfe, Assoc. General Counsel, Specialty IP Litigation

For Cipla: Aarti Deodhar
Pinakin Karpe
Anagha Tendulkar

- (c) Outside experts or consultants retained by outside counsel for purposes of this action, provided such expert or consultant has (i) executed the non-disclosure agreement in the form attached hereto as Exhibit A and (ii) has provided the

executed copy of Exhibit A to the opposing party; and the receiving party and expert or consultant have complied with the requirements of Paragraph 10, below.

- (d) Secretarial, paralegal, clerical, duplicating and data processing personnel of the foregoing;
- (e) The Court and court personnel;
- (f) Any deponent may be shown or examined on any information, document or thing designated Confidential if it appears that the witness authored or received a copy of it, was involved in the subject matter described therein or is, or was at the time the document was created, employed by the party who produced the information, document or thing, is an officer, Rule 30(b)(6) designee, or retained expert for the producing party, or if the producing party consents to such disclosure;
- (g) Persons, organizations, or vendors retained by or for the parties to assist in preparing for pretrial discovery, trial and/or hearings including, but not limited to, translators, interpreters, court reporters, litigation support personnel, document copying/scanning/printing/hosting/review vendors, jury consultants, individuals to prepare demonstrative and audiovisual aids for use in the courtroom or in depositions or mock jury sessions, as well as their staff, stenographic, and clerical employees whose duties and responsibilities require access to such materials.

7. Confidential material shall be used only by individuals permitted access to it under Paragraph 6. Confidential material, copies thereof, and the information contained therein, shall not be disclosed in any manner to any other individual, until and unless (a) outside counsel for the party asserting confidentiality waives the claim of confidentiality, in writing, or (b) the Court orders such disclosure.

8. With respect to any depositions that involve a disclosure of Confidential material of a party to this action, such party shall have until thirty (30) days after receipt of the deposition transcript within which to inform all other parties that portions of the transcript are to be designated Confidential, which period may be extended by agreement of the parties. Until the lapse of said thirty (30) days, or until being informed that certain portions of the deposition are to be designated as Confidential, the deposition transcript and the contents of the deposition shall be treated as Confidential. Upon being informed that certain portions of a deposition are to be designated as Confidential, all parties shall immediately cause each copy of the transcript in its custody or control to be appropriately marked and limit disclosure of that transcript in accordance with this Order.

9. Nothing in this Order shall preclude counsel from examining a witness to determine whether they authored or have prior knowledge or authorized access to Confidential material, so long as the examination is conducted in a manner that does not disclose the details of the material or information designated as Confidential.

10. Prior to a party's giving, showing, disclosing, making available or communicating Confidential material to any expert or consultant under Paragraph 6(c) above, the party shall:

- (a) Serve a notice on all other parties, identifying (1) the expert or consultant and the expert's or consultant's (2) business address, (3) business telephone numbers, (4) present employer and position (along with a job description), (5) consulting activities and job history for the past five years, and (6) past or present relationship, if any, with any parties in the above-captioned action and (7) a list of all matters in which the expert or consultant has testified at a hearing, at a trial, or by deposition in the last four years. Furthermore, the most recent curriculum vitae

or resume of the expert or consultant shall be provided under this subparagraph. If the most recent curriculum vitae or resume of the expert or consultant provides the information required under this paragraph, then the information need not be separately provided.

- (b) Provide an executed copy of Exhibit A on all other parties. The notified parties shall be entitled to object to disclosure of Confidential material to the expert or consultant within 4 business days after receipt of notice by stating specifically in writing the reasons why such expert or consultant should not receive Confidential material.
- (c) If the parties are unable to agree on disclosure to the expert or consultant, the party objecting to such expert or consultant may apply to the Court for an order that disclosure is improper within 4 business days of the parties reaching an impasse. The burden of establishing the validity of such written objections rests with the objecting party. If the objecting party does not apply to the Court within the prescribed period, the objection shall be deemed withdrawn.
- (d) No disclosure of Confidential material shall be made to the proposed expert or consultant until the time for serving objections to that expert or consultant has passed, or, in the event that a written objection is timely served and a motion to prevent disclosure is filed, until such time as the Court has made a ruling thereon, and then, only in accordance with such ruling.
- (e) The filing and pendency of objections shall not limit, delay, or defer any disclosures of Confidential material to persons as to whom no such objection has been made, nor shall it delay or defer any other pending discovery unless the level

of confidentiality bears directly on the objecting party's ability to conduct such discovery.

11. Discovery of communications between counsel and any independent expert or consultant retained or specially employed by that counsel for purposes of this litigation shall be limited to the factual information, analyses, documents, and/or data relied on by the expert in rendering the opinions expressed in an expert report or at trial. Except as otherwise provided herein, all communications between counsel and the expert relating to the process of preparing an expert report or developing opinions for trial, including all preliminary or draft reports, expert working papers, notes, and communications relating thereto, shall be deemed exempt from discovery and use at trial.

12. If counsel for a party receiving documents or information designated as Confidential hereunder objects to such designation of any or all of such items, the following procedure shall apply:

- (a) Counsel for the objecting party shall serve on the designating party or third party a written objection to such designation, which shall describe with particularity the documents or information in question and shall state the grounds for objection. Counsel for the designating party or third party shall respond in writing to such objection within 14 days, and shall state with particularity the grounds for asserting that the document or information is Confidential. If no timely written response is made to the objection, the challenged designation will be deemed to be void. If the designating party or nonparty makes a timely response to such objection asserting the propriety of the designation, counsel shall then confer in good faith in an effort to resolve the dispute.

(b) If a dispute as to a Confidential designation of a document or item of information cannot be resolved by agreement, the proponent of the designation being challenged shall present the dispute to the Court initially by ~~telephone~~ or letter, in accordance with Local Civil Rule 37.1(a)(1), before filing a formal motion for an order regarding the challenged designation. The document or information that is the subject of the filing shall be treated as originally designated pending resolution of the dispute. Upon challenge of a designation, the designating party bears the burden of proof.

13. All requests to seal documents filed with the Court shall comply with Local Civil Rule 5.3.

14. If the need arises during trial or at any hearing before the Court for any party to disclose Confidential information, it may do so only after giving notice to the producing party and as directed by the Court.

15. To the extent consistent with applicable law, the inadvertent or unintentional disclosure of Confidential material that should have been designated as such, regardless of whether the information, document or thing was so designated at the time of disclosure, shall not be deemed a waiver in whole or in part of a party's claim of confidentiality, either as to the specific information, document or thing disclosed or as to any other material or information concerning the same or related subject matter. Such inadvertent or unintentional disclosure may be rectified by written notification to counsel for all parties to whom the material was disclosed that the material should have been designated Confidential within a reasonable time after disclosure. Such notice shall constitute a designation of the information, document or thing as Confidential under this Discovery Confidentiality Order.

16. When the inadvertent or mistaken disclosure of any information, document or thing protected by privilege or work-product immunity is discovered by the producing party and brought to the attention of the receiving party, the receiving party's treatment of such material shall be in accordance with Federal Rule of Civil Procedure 26(b)(5)(B). Pursuant to Federal Rule of Evidence 502, the inadvertent or mistaken disclosure of such privileged information, document or thing shall not by itself constitute a waiver by the producing party of any claims of privilege or work-product immunity. In the event a party or non-party seeks to withdraw the production of inadvertently produced information, documents or things protected by privilege or work-product immunity, the following procedures must be followed:

- (a) After recognizing that privileged information has been inadvertently produced or disclosed, the party who made the inadvertent production or disclosure shall send to each receiving party a written request for return of the inadvertently produced or disclosed document or thing promptly after discovering that the privileged information has been produced or disclosed.
- (b) Within five (5) business days of receiving such a request, the receiving party shall
 - (a) return to the producing party all such documents and things identified by the producing party as being protected by privilege or work-product immunity and as having been inadvertently produced and (b) delete any electronic records thereof (with the exception of back-up tapes or other archival media, which should be treated in accordance with standard retention policies). The receiving party shall not utilize the information contained in the inadvertently produced documents or things for any purpose, or disseminate or transmit such information, except as provided below in Subparagraphs 16(c)-16(e).

- (c) If the receiving party wishes to contest that any such document or thing is protected by privilege or work product immunity, the receiving party shall so notify the producing party in writing when the document or thing is returned to the producing party ("Notice of Contest"). The receiving party may retain one (1) copy of the document(s) or thing(s) at issue for the sole purposes of filing a motion to contest the designation. The copy returned by the receiving party must be sequestered, and may not be used for any purpose except to present the information to the Court for a determination of the claim of privilege.
- (d) Within three (3) business days after receiving the Notice of Contest, the producing party shall provide to the receiving party for each document or thing a description of the basis for the claim of privilege or immunity.
- (e) Within five (5) business days after receiving such description, the receiving party may seek relief from the Court to compel production of such documents and things, the protection of which is still disputed, in accordance with the Court's procedures for resolution of discovery disputes. If resolution is not sought from the Court within such five (5) business day period, the one (1) copy, if any retained by the receiving party as set forth in Subparagraph 16(c) above shall be immediately returned to the producing party. Likewise, in the event that the Court rejects the receiving party's challenge to the privileged status of the inadvertent production, the one (1) copy, if any, retained by the receiving party as set forth in Subparagraph 16(c) above shall be immediately destroyed or returned to the producing party.

- (f) If there is no Notice of Contest or in the event the Court rejects any challenge by the receiving party to the privileged status of the inadvertent production, the receiving party shall either destroy any documents or things containing information derived from the inadvertent production, or else redact or otherwise permanently delete the inadvertently produced information from those documents or things.

17. No information that is in the public domain or which is already known by the receiving party through proper means or which is or becomes available to a party from a source other than the party asserting confidentiality, rightfully in possession of such information on a nonconfidential basis, shall be deemed or considered to be Confidential material under this Discovery Confidentiality Order.

18. This Discovery Confidentiality Order shall not deprive any party of its right to object to discovery by any other party or on any otherwise permitted ground. This Discovery Confidentiality Order is being entered without prejudice to the right of any party to move the Court for modification or for relief from any of its terms.

19. This Discovery Confidentiality Order shall survive the termination of this action and shall remain in full force and effect unless modified by an Order of this Court or by the written stipulation of the parties filed with the Court.

20. In the event Confidential information disclosed during the course of this Action is sought by any person or entity not a party to the Action, whether by subpoena in another action or service with any legal process, the party receiving such subpoena or service shall promptly notify in writing outside counsel for the Designating Party if such subpoena or service demands the production of Confidential information of such Designating Party. Any person or entity

seeking such Confidential information by attempting to enforce such subpoena or other legal process shall be apprised of this Protective Order by outside counsel for the party upon whom the subpoena or process was served. Nothing herein shall be construed as requiring anyone covered by this Protective Order to contest a subpoena or other process, to appeal any order requiring production of Confidential information covered by this Protective Order, or to subject itself to penalties for non-compliance with any legal process or order.

21. Within sixty (60) days of the final conclusion of this litigation, including the exhaustion of all appeals therefrom and all related proceedings, each party or other individual subject to the terms hereof shall be under an obligation to assemble and destroy or return to the originating source all originals and unmarked copies of documents and things containing Confidential material. Notwithstanding the above, counsel may retain those materials in their files that contain or reflect Confidential information but which also constitute or reflect counsel's work product. Counsel shall also be entitled to retain complete copies of all transcripts, pleadings (including exhibits), motion papers (including exhibits), and the trial record (including exhibits) even if such materials contain Confidential information, so long as such materials are marked with the appropriate designation, subject to the provisions of this Order. Notwithstanding the foregoing, no party shall be obligated to return or destroy Confidential information that may be contained on electronic backup tapes or other archival media, which should be treated in accordance with standard retention policies (i.e., overwritten in due course).

22. If a non-party provides discovery to any party in connection with this Action, and if the non-party so elects, then the provisions of this Order shall apply to such discovery and the parties will treat all information that is produced by such non-party in accordance with the terms of this Order. Under such circumstances, the non-party shall have the same rights and obligations

under this Order as held by the parties to this Action. Because non-parties may be requested to produce documents embodying, containing, or reflecting a party's Confidential material, a party may designate non-party documents as Confidential. At the written request of any party, all documents produced by a non-party in this action shall be treated as if designated Confidential hereunder for a period of thirty (30) days after production, in order to allow the parties time to review the documents and make any appropriate designations.

23. This Order may be modified only by written agreement of all parties or further order of the Court and is without prejudice to the rights of any party or third party to seek additional or different relief from the Court not specified in this Order.

24. All parties shall be bound by the terms of the Order once submitted to the Court.
IT IS SO STIPULATED AND AGREED this 16th day of August, 2024:

/s/ Loly G. Tor

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IT IS SO ORDERED.

Dated: 8/19/24

Hon. Michael A. Hammer, U.S.M.J.

SO ORDERED

s/Michael A. Hammer

Michael A. Hammer, U.S.M.J.

Date: 8/19/24

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Defendants.

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Civil Action No. 24-7162 (SRC)(MAH)

EXHIBIT A TO THE DISCOVERY CONFIDENTIALITY ORDER

I, _____, being duly sworn, state that:

1. My address is _____.
2. My present employer is _____, and the address of my
present employment is _____.
3. My present occupation or job description is _____.

4. I have carefully read and understood the provisions of the Discovery Confidentiality Order in this case signed by the Court, and I will comply with all provisions of the Discovery Confidentiality Order.
5. I will hold in confidence and not disclose to anyone not qualified under the Discovery Confidentiality Order any Confidential material or any words, summaries, abstracts, or indices thereof disclosed to me.
6. I will limit use of Confidential material disclosed to me solely for purpose of this action.
7. No later than the final conclusion of the case, I will return or destroy all Confidential material and summaries, abstracts, and indices thereof which come into my possession, and documents or things which I have prepared relating thereto, to counsel for the party for whom I was employed or retained.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: _____ [Name] _____